I. Claims 33-64, 78-89 and 82-92, drawn to a method of treating cancer using a jatrophane compound, or derivative or salt thereof, classified in class 514, subclass 100+.

II. Claims 33, 34, 65-69, 78-89 and 94-99, drawn to a method of treating cancer using a pepluane compound or derivative or salt thereof, classified in class 514, subclass 100+.

III. Claims 33, 34, 70-73, 78-89 and 94-99, drawn to a method of treating cancer using a paraliane compound, or derivative or salt thereof, classified in class 514, subclass 100+.

IV. Claims 33, 34, 74-89 and 94-99, drawn to a method of treating cancer using an angeloyl-substituted ingenane compound, or derivative or salt thereof, classified in class 514, subclass 100+.

V. Claims 90-93, drawn to a method of treating cancer via administering an effective amount of at least two compounds (selected from numerous compounds recited therein), classified in class 514, subclass 100+.

In support of the Restriction Requirement, the Office Action alleges that the methods of Groups I-IV comprise in vivo administration of mutually exclusive compounds and conclude that they are distinct and different. It further alleges that the method of Group V is different and distinct from Groups I-IV, stating that the methods of Groups I-IV require the administration of an effective amount of one active compound, wherein the method of Group V requires the administration of an effective amount of a combination of at least two bioactive

compounds which, according to the Office Action, do not necessarily include the singular compound of any one of Groups I-IV.

In order to be responsive, applicant elects, with traverse, the subject matter of Group IV, i.e., Claims 33, 34, 74-89 and 94-99 for continued prosecution herein. Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter.

Nevertheless, applicant hereby traverses, pursuant to 37 C.F.R. §§1.111 and 1.143, the requirement for restriction and requests reconsideration thereof in view of the following remarks.

Applicant respectfully requests that the Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. §121 and 37 C.F.R. §§1.141 - 1.142.

35 U.S.C. §121 provides that the Commissioner may restrict an application when two or more independent and distinct inventions are claimed in a single application. (Emphasis added). Similarly, 37 C.F.R. §1.141(a) permits restriction conditioned upon a finding that independent and distinct inventions are found within one application. Applicant respectfully submits that the Office Action has not made out a prima facie case to support a restriction requirement between Groups I-V for it has not shown that Groups I-V are independent.

Only the statutory requirement that the claims of the various groups are distinct from each has been proffered as the basis for the requirement of restriction between Groups I and I-V. Even assuming, pro arguendo, that the Office Action is correct with respect to distinctiveness, there is absolutely no indication in the Office Action that Groups I- V are also

independent. In fact, Applicant submits that there is interdependence between each alleged group of claims.

MPEP §802.01 defines independent as follows:

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect...

Applicant respectfully submits that the subject matter in Groups I-V is "connected in design, operation or effect" and are thus not independent.

The subject matter of all of the claims is related to the administration to a subject of an effective amount of a compound derived from the sap of a species of Euphorbia, wherein the compound

(a) is extractable from the Euphorbia sap in the presence of about 95% v/w ethanol,

(b) has cell inhibiting or retarding activity which is neither destroyed by acetone nor by heating about 95°C for about 15 minutes, and

(c) is capable of inhibiting the growth of at least one cell line selected from the group consisting of MM96L, MM229, MM220, MM537, MM2058, HeLa, B16, LIM1215, A549, MCF7, MCC16 and Colo16. Each of the various compounds, viz., the jatrophane compound, pepluane compound, paraliane compound and angeloyl-substituted ingenane compound or derivative or salt of any of the aforementioned compounds fall within the above-description. Thus, each of the compounds are related to one another.

In addition, the subject matter of all claims relates to a method of treating cancer and utilizing these compounds.

Thus the subject matter in Groups I-V have a disclosed relationship. Since the Office Action has not alleged the statutory required independence of the groups and further because these groups of claims are connected in design, operation and/or effect, and are therefore not independent, the claims which the Office Action has grouped separately are not "independent and distinct" so as to justify the restriction requirement. It is therefore respectfully submitted that the Restriction Requirement is improper and cannot be maintained.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicant has done herein, so as to encourage applicants to provide a more detailed disclosure of all aspects of their invention. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

Applicant respectfully suggests that in view of the continued increase of official fees and the potential limitation of applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravenes the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), the applicant is required to either conduct simultaneous prosecution with attendant filing fees and costs or face a compromise of the term of his patent assets.

Then, it is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon does not provide comfort against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention-double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicant respectfully urges the Examiner not to require restriction in cases such as the present application.

Applicant respectfully submits that the present restriction requirement is not proper for still another reason; the groupings of the claims are not in compliance with the MPEP. Contrary to the allegations in the Office Action, the subject matter of Groups I-V have the same classification (Class 514, subclass 100+). Moreover, they do not have a different field of search, nor is there any showing that they have a different field of search. Further, there is no clear identification of separate future classification or field of search. Under these circumstances, according to the MPEP, no reasons exist for dividing among the related invention. MPEP §808.02. Thus, in accordance with MPEP §808.02, there should be no restriction imposed between Groups I-V. Consequently, inasmuch as the restriction requirement is not in conformance with the MPEP the applicant respectfully submits that for still another reason, the restriction requirement should be withdrawn.

Hence, it is respectfully requested that the United States Patent and Trademark Office reconsider and withdraw the requirement for restriction pursuant to 35 U.S.C. §121 and provide an action on the merits with respect to all of the claimed subject matter.

Respectfully submitted,

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